

Application No.: 10/072,320

Response to Office Action  
Mailed December 23, 2008**In the Claims**

The following listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims:**

1-32 (Canceled).

33. (Currently Amended) A bi-layer wax-film composite ~~comprising a pH-sensitive mucoadhesive layer bonded to a water-insoluble wax layer, the bi-layer wax film composite~~ having a total thickness of less than 5 mm, comprising:

(a) a pH-sensitive mucoadhesive layer, comprising:

(1) at least one water-insoluble swellable mucoadhesive polymer; and

(2) at least one pH-sensitive film-forming polymer;

(b) a water-insoluble wax layer bonded to the pH-sensitive mucoadhesive layer; and

(c) at least one molecule of interest.

34. (Original) The wax-film composite of claim 33, wherein the pH-sensitive mucoadhesive layer is present at a concentration of 20% to 90% by weight, and the water-insoluble wax layer is present at a concentration of 10% to 80% by weight.

35. (Currently Amended) The wax-film composite of claim 33, wherein said pH-sensitive mucoadhesive layer further comprises[[:]]

~~at least one water-insoluble swellable mucoadhesive polymer;~~

~~at least one pH-sensitive film-forming polymer; and~~

at least one molecule of interest.

36. (Previously Presented) The wax-film composite of claim 35, wherein the water-insoluble swellable mucoadhesive polymer is polyacrylic acid cross-linked with polyalkenyl ether or divinyl glycol.

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37. (Previously Presented) The wax-film composite of claim 35, wherein the water-insoluble swellable mucoadhesive polymer is Noveon or Carbomer.

38. (Currently Amended) The wax-film composite of claim 35, wherein the water-insoluble swellable mucoadhesive polymer is Noveon and is present in the pH-sensitive mucoadhesive layer at a concentration from 0.1% to 20% by weight 33% to 80% w/w.

39. (Previously Presented) The wax-film composite of claim 35, wherein the pH-sensitive film-forming polymer present in the pH-sensitive mucoadhesive layer is a copolymer of methacrylic acid and acrylic or methacrylic ester.

40. (Currently Amended) The wax-film composite of claim 35, wherein the pH-sensitive film-forming polymer is Eudragit and is present in the pH-sensitive mucoadhesive layer at a concentration from 0.05% to 10% by weight 20% to 67% w/w.

41. (Previously Presented) The wax-film composite of claim 35, wherein the pH-sensitive film-forming polymer present in the pH-sensitive mucoadhesive layer is a Eudragit polymer, or chemical derivative thereof.

42. (Original) The wax-film composite of claim 33, wherein the water-insoluble wax layer comprises at least one water-insoluble pharmaceutical wax having a melting point between 40° C and 100° C and at least one water-soluble or water-swellaable polymer.

43. (Original) The water-insoluble pharmaceutical wax of claim 42, wherein said wax is DENTSPLY® Utility Wax, beeswax, emulsifying wax, microcrystalline wax, carnauba wax, paraffin wax, white wax, yellow wax, or other suitable pharmaceutical wax.

44. (Previously Presented) The water-soluble or swellable polymer of claim 42, wherein said polymer is present in the insoluble wax layer at a concentration from 0.05% to 10% by weight.

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45. (Original) The water-soluble or swellable polymer of claim 42, wherein said water-soluble or water-swellable polymer is tragacanth, polyvinyl[[,]] pyrrolidone, polyvinyl alcohol, cross-linked polyacrylic acid, polyethylene glycol, a cellulose polymer derivative, or other suitable pharmaceutical polymer that is water-soluble or water-swellable.

46. (Previously Presented) The wax-film composite of claim 35, wherein the molecule of interest is contained in and released from either the pH-sensitive mucoadhesive layer or the water-insoluble wax layer.

47. (Previously Presented) The wax-film composite of claim 35, wherein the molecule of interest comprises an active pharmaceutical compound such as an antimicrobial, antiviral, antiinflammatory, antiseptic, antihistamine, a local anesthetic, a disinfectant, a keratolytic, an analgesic, an anti-migraine, anti-fungal, a sweetener, a flavoring agent, a diagnostic agent, or a combination thereof.

48. (Withdrawn) The wax-film composite of claim 33, wherein the molecule of interest is amlexanox.

49. (Withdrawn) The wax-film composite of claim 33, wherein the molecule of interest is triclosan.

50. (Withdrawn) The wax-film composite of claim 33, wherein the molecule of interest is lidocaine, benzocaine, or dyclonine.

51. (Previously Presented) The wax-film composite of claim 35, wherein the molecule of interest is a peptide or protein.

52. (Withdrawn) The wax-film composite of claim 33, wherein the molecule of interest is at least one benzodiazepine drug or derivative thereof.

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53. (Withdrawn) The wax-film composite of claim 33, wherein the molecule of interest is hirudin or hirudin complexed with a substance of opposite charge.

54. (Withdrawn) The wax-film composite of claim 53, wherein said substance of opposite charge is chitosan or protamine.

55. (Withdrawn) The wax-film composite of claim 33, wherein the molecule of interest is plasmid DNA or plasmid DNA complexed with a substance of opposite charge such as chitosan, protamine, or a cationic lipid.

56. (Previously Presented) The wax-film composite of claim 33, wherein the wax-film composite is applied to an application site comprising: the skin, mouth, vagina, nasal cavity, or other accessible mucosal site.

57. (Previously Presented) The wax-film composite of claim 56, wherein the wax-film composite adheres to the application site for at least one hour.

58-62. (Canceled)